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| EXAMINER | |
|---|---|
| NOGUEROLA, ALEXANDER STEPHAN | |
| ART UNIT | PAPER NUMBER |
| 1795 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/522,830 | ANSELMETTI ET AL. | |
| | Examiner | Art Unit | |
| | ALEX NOGUEROLA | 1795 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *9/23/2008 (election)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *13-16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4-6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Koutny et al. "On-Line Detection of Proteins in Gel Electrophoresis by Ultraviolet Absorption and by Native Fluorescence Utilizing a Charge-Coupled Device Imaging System," Anal. Chem. 1993, 65, 183-187 ("Koutny").

Addressing claim 1, Koutny discloses a device possessing the following components:

a) a UV source (UV – Figure 1) for excitation light in the wavelength range from 140 to 320 nm (last paragraph in the first column on page 184 "For native fluorescence … hand-held UV lamp, operating at 254 nm);

b) a separation medium (GEL – Figure 1) for a flat-bed electrophoretic separation of electrically charged substances (Figures 1 and 2);

c) regions, which are distributed in the separation medium (2), of substances which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (the first full paragraph in the first column on page 184 – "In all cases, 5 μl of sample was loaded in each well" and Figure 2), UV fluorescence in the wavelength range from 150 to 400 nm (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185);

d) a UV detector (CCD – Figure 1) for the UV fluorescence radiation (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (DF, QL – Figure 1).

Addressing claim 2, for the additional limitation of this claim see the last paragraph in the first column on page 184 (UV lamp).

Addressing claim 4, for the additional limitation of this claim see the last paragraph in the first column on page 184 (UV lamp operating at 254 nm).

Addressing claims 5 and 6, for the additional limitation of these claims see the first paragraph in the first column on page 184 (agarose).

Addressing claim 8, for the additional limitation of this claim note PT and QP in Figure 1.

Addressing claim 9, for the additional limitation of this claim see the first full paragraph in the second column on page 183, which mentions tryptophan and tyrosine groups, and the ACS Registry entries for tryptophan and tyrosine, which show the chemical structures of these compounds.

Addressing claims 10 and 11, for the additional limitations of these claims see the first full paragraph in the second column on page 183

Addressing claim 12, for the additional limitation of this claim see Figure 1 (CCD).

3. Claims 1, 2, 4-6, and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hassard et al. US 6,613,210 B1 ("Hassard").

Addressing claim 1, Hassard discloses a device possessing the following components:

a) a UV source (121 – Figure 12) for excitation light in the wavelength range from 140 to 320 nm (col. 03:63 – col. 04:03 and col. 04:23-30);

b) a separation medium (col. 09:03-11) for a flat-bed electrophoretic separation of electrically charged substances (col. 09:03-11);

c) regions, which are distributed in the separation medium (2), of substances which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (col. 09:15-26 and col. 03:45-54), UV fluorescence in the wavelength range from 150 to 400 nm (col. 04:36-47);

d) a UV detector (130) for the UV fluorescence radiation (col. 09:12-15); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (128, 129).

Addressing claim 2, for the additional limitation of this claim see col. 09:03-06.

Addressing claim 4, for the additional limitation of this claim see col. 03:63 – col. 04:03 and col. 04:30-31.

Addressing claims 5 and 6, for the additional limitations of these claims see col. 05:28-29.

Addressing claim 8, for the additional limitation of this claim see col. 09:03-11.

Addressing claims 9 and 10, for the additional limitation of these claims see col. 04:23-31.

Addressing claims 11 and 12, for the additional limitations of these claims see col. 04:36-47.

4. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schriftman, "Analysis of Pharmaceuticals by Ultraviolet Densitometry on Thin-Layer Chromatograms I – Parabens in Gels and Creams," Journal of Pharmaceutical Sciences (1968), 57(10), 1760-3 ("Schriftman").

Addressing claim 1, Schriftman discloses a device possessing the following components:

a) a UV source (abstract; **Experimental – Equipment** on page 1761; and **Summary** on page 1762) for excitation light in the wavelength range from 140 to 320 nm (254 mμ in **Experimental – General Procedure** on page 1761);

b) a separation medium (at least silica thin layer gels - abstract) for a flat-bed chromatographic separation of electrically charged substances (abstract; that the substances are electrically charged is an intended use for which the separation medium is capable performing);

c) regions, which are distributed in the separation medium, of substances which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (Figure 1), UV fluorescence in the wavelength range from 150 to 400 nm (485 mμ in **Experimental – General Procedure** on page 1761);

d) a UV detector for the UV fluorescence radiation (abstract; **Experimental – Equipment** on page 1761; and **Experimental – General Procedure** on page 1761); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (485 mμ color filter in **Experimental – General Procedure** on page 1761).

Addressing claim 7, for the additional limitation of this claim see the title and abstract.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koutny et al. "On-Line Detection of Proteins in Gel Electrophoresis by Ultraviolet Absorption and by Native Fluorescence Utilizing a Charge-Coupled Device Imaging System," Anal. Chem. 1993, 65, 183-187 ("Koutny").

Addressing claim 3, Koutny discloses a device possessing the following components:

a) a UV source (UV – Figure 1) for excitation light in the wavelength range from 140 to 320 nm (last paragraph in the first column on page 184 "For native fluorescence … hand-held UV lamp, operating at 254 nm);

b) a separation medium (GEL – Figure 1) for a flat-bed electrophoretic separation of electrically charged substances (Figures 1 and 2);

c) regions, which are distributed in the separation medium (2), of substances which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (the first full paragraph in the first column on page 184 – "In all cases, 5 μl of sample was loaded in each well" and Figure 2), UV fluorescence in the wavelength range from 150 to 400 nm (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185);

d) a UV detector (CCD – Figure 1) for the UV fluorescence radiation (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (DF, QL – Figure 1).

Koutny does not mention the energy density exhibited by the UV source; however, since the purpose of the UV source is to emit light that will cause native fluorescence of one or more substances in the separation medium one with ordinary skill in the art would try different energy levels until the threshold for UV excitation of the substance of interest is reached, but not so high as to cause undue heating or molecular disruption of the substance. Moreover, based on a 30-W UV lamp and a 1 square inch band pass filter with 13% transmittance (last paragraph in the first column on page 184) the energy density of the UV system in Koutny is 600 mJ/(s x $cm^2$), which is comparable to the claimed range.

Addressing claim 17, Koutny discloses a device possessing the following components:

a) a UV source (UV – Figure 1) for excitation light in the wavelength range from 140 to 320 nm (last paragraph in the first column on page 184 “For native fluorescence … hand-held UV lamp, operating at 254 nm);

b) a separation medium (GEL – Figure 1) for a flat-bed electrophoretic separation of electrically charged substances (Figures 1 and 2);

c) regions, which are distributed in the separation medium (2), of substances

which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (the first full paragraph in the first column on page 184 – "In all cases, 5 μl of sample was loaded in each well" and Figure 2), UV fluorescence in the wavelength range from 150 to 400 nm (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185);

d) a UV detector (CCD – Figure 1) for the UV fluorescence radiation (the first full paragraph in the second column on page 183 and the last paragraph in the first column on page 185); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (DF, QL – Figure 1).

Koutny does not mention using the device for separating and determining disease-specific substances in samples taken from the human or animal body or from plants; however, Koutny does use albumin samples taken from a chicken and from an human (Experimental Section – Gel Electrophoresis)

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassard et al. US 6,613,210 B1 ("Hassard").

Hassard discloses a device possessing the following components:

a) a UV source (121 – Figure 12) for excitation light in the wavelength range from 140 to 320 nm (col. 03:63 – col. 04:03 and col. 04:23-30);

b) a separation medium (col. 09:03-11) for a flat-bed electrophoretic separation of electrically charged substances (col. 09:03-11);

c) regions, which are distributed in the separation medium (2), of substances which are to be separated and which have been separated and which are also unlabelled, which substances emit, on excitation with the said UV source (col. 09:15-26 and col. 03:45-54), UV fluorescence in the wavelength range from 150 to 400 nm (col. 04:36-47);

d) a UV detector (130) for the UV fluorescence radiation (col. 09:12-15); and

e) optical or optoelectronic components for filtering, guiding and/or amplifying the excitation radiation and the fluorescence radiation (128, 129).

Hassard does not mention the energy density exhibited by the UV source; however, since the purpose of the UV source is to emit light that will cause native fluorescence of one or more substances in the separation medium one with ordinary skill in the art would try different energy levels until the threshold for UV excitation of the substance of interest is reached, but not so high as to cause undue heating or molecular disruption of the substance.

***International Search Report for International Application No. PCT/EP03/50350 ("Search Report")***

10. Only "A" references are listed in the Search Report.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
December 29, 2008